

US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 101101

Date Out of EFGWB: DEC 28 1988

TO: Rubis - GCSB, PM 25
Registration Division (TS-769C)

FROM: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #2
Environmental Fate and Ground Water Branch/EFED (TS-769C)

THRU: Hank Jacoby, Chief (acting)
Environmental Fate and Ground Water Branch/EFED (TS-769C)

Attached, please find the EFGWB review of . . .

Reg./File #: 235782

Chemical Name: Metribuzin

Type Product: Herbicide

Company Name: Mobay Corp.

Purpose: Request for extension of data requirement

Date Received: 12-12-88 Action Code: 400

Date Completed: 12-27-88 EFGWB # (s): 90197

Total Reviewing time (decimal days): 0.5 days

Deferrals to: ☐ Ecological Effects Branch, EFED
☐ Science Integration & Policy Staff, EFED
☐ Non-Dietary Exposure Branch, HED
☐ Dietary Exposure Branch, HED
☐ Toxicology Branch, HED

12/10/88
48749 EFED

Page No. _____
Date Received _____
12/15/88 EFED ATTACH

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

Confidential Business Information-Does Not Contain National Security Information(E.O. 1201)
This form is to be used for individual studies and for submission of pesticide application

1. PRODUCT NAME <i>Metribuzin</i>		3. RECORD NUMBER <i>235782</i>		4. ACTION CODE <i>400 1</i>		5. MRID/ACCESSION NUMBER <i>165-2</i>		6. STUDY GUI OR NARRAT	
2. IDENTIFYING NUMBER <i>101101</i>									
7. REFERENCE NUMBER <i>5</i>		8. DATE RECEIVED (EPA) <i>10/5/88</i>		9. PRODUCT/REVIEW MANAGER/DCI <i>Rubio-GCSB</i>		10. PM/RM TEAM NUMBER <i>25</i>		11. DATE SENT (HED/EFED/BEAD) <i>12/16/88</i>	
12. PROJECTED RETURN DATE <i>12/16/88</i>		13. DATE RETURNED TO (RD/SRRD)		INSTRUCTIONS: <i>time regarding field studies</i>					

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

14. CHECK APPLICABLE BOX:

- ☐ ADVERSE 6(a)(2) DATA (405) ☐ SPECIAL REVIEW DATA (870) ☐ GENERIC DATA (REREGISTRATION) (660) ☐ PRODUCT SPECIFIC DATA (REREGISTRATION)

15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

16. HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

17. RELATED ACTIONS:
Extension of T...

18. TO	TYPE OF REVIEW		19. REVIEWERS ALSO SENT TO	20. DATA REVIEW CRITERIA	
HED	<input type="checkbox"/> SCIENCE ANALYSIS & COORD.	<input type="checkbox"/> SAC	<input type="checkbox"/> PC <input type="checkbox"/> PL <input type="checkbox"/> EA <input type="checkbox"/> AC <input type="checkbox"/> BA	A. Policy Note #31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements	
	<input type="checkbox"/> TOXICOLOGY/HFA	<input type="checkbox"/> TOX/HFA			
	<input type="checkbox"/> TOXICOLOGY/IR	<input type="checkbox"/> TOX/IR			
	<input type="checkbox"/> DIETARY EXPOSURE	<input type="checkbox"/> DEB			
SRD	<input type="checkbox"/> NON-DIETARY EXPOSURE	<input type="checkbox"/> NDE	<input type="checkbox"/> EEB <input type="checkbox"/> EFGWB	B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18	
	<input checked="" type="checkbox"/> ECOLOGICAL EFFECTS	<input type="checkbox"/> SR			C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
	<input checked="" type="checkbox"/> ENVIRONMENTAL FATE & GROUND H2O	<input type="checkbox"/> RER			
	<input type="checkbox"/> SPECIAL REVIEW	<input type="checkbox"/> GSC			
RD	<input type="checkbox"/> REREGISTRATION	<input type="checkbox"/> IR	<input type="checkbox"/> FH <input type="checkbox"/> AM		
	<input type="checkbox"/> GENERIC CHEMICAL SUPPORT	<input type="checkbox"/> EAB			
	<input type="checkbox"/> INSECTICIDE-RODENTICIDE				
	<input type="checkbox"/> FUNGICIDE-HERBICIDE				
BEAD	<input type="checkbox"/> ANTIMICROBIAL				
	<input type="checkbox"/> PRODUCT CHEMISTRY				
	<input type="checkbox"/> PRECAUTIONARY LABELING				
	<input type="checkbox"/> ECONOMIC ANALYSIS				
	<input type="checkbox"/> ANALYTICAL CHEMISTRY				
	<input type="checkbox"/> BIOLOGICAL ANALYSIS				

☐ CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS) ☐ LABEL ATTACHED

White - Data Coordinator
Yellow - Data Review Section
Green - Return with completed review
Pink - PM/RM/DCI
Include original + two (2) copies with each submission

1. CHEMICAL: Common name:

Metribuzin

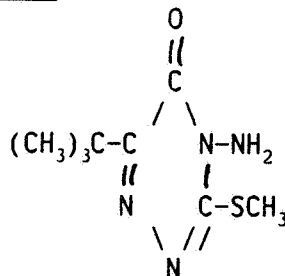
Chemical name:

4-Amino-6-tert-butyl-3(methylthio)-1,2,4-triazin-5(4H)-one.

Trade name(s):

Lexone, Sencor, Sencoral, Sencorex, Bay Dic 1468, Bay 94337.

Structure:



Formulations: Lexone 4L, Lexone DF, Sencor 4, Sencor DF.

Physical/Chemical properties:

Molecular formula: $C_8H_{14}N_4OS$

Molecular weight: 214.3.

Physical state: White crystalline solid.

Melting Point: 125-126.5°C.

Solubility: (20°C): 1.2 g/l water; 820 g/kg acetone; 220 g/kg benzene; 850 g/kg chloroform; 1 kg/kg cyclohexanone; 190 g/kg ethanol; 2 g/kg hexane; 120 g/kg toluene.

2. STUDY/ACTION TYPE:

Request for extension of timeframe for submission of field accumulation on rotational crops study (§165-2).

3. STUDY IDENTIFICATION:

Letter of request from John S. Thornton, Mobay Corp. to OCM (EN-342) dated Sept. 30, 1988.

4. REVIEWED BY:

A. Reiter, Chemist
Environmental Chemistry Review Section II
EFGWB/EFED/OPP

A. Reiter
Date: December 27, 1988

5. APPROVED BY:

E. Regelman, Supervisory Chemist
Environmental Chemistry Review Section II
EFGWB/EFED/OPP

Date:


DEC 28 1988

6. CONCLUSIONS:

The registrant is correct in finding error with the assignment of footnote 15A to §165-1 (Confined Accumulation Study) in Table A of the Registration Standard. This branch's science chapter did not make such a statement and it reiterates its policy as expressed in 40 CFR Part 158 that a field accumulation study is required if significant residue is likely to be present in soil at the time of crop planting, as evidenced by residue data obtained from the confined accumulation study (§165-1).

Furthermore, the registrant is correct in requesting that the field study be reserved until after this branch completes its review of the confined accumulation study.

7. RECOMMENDATIONS:

The registrant should be informed that the Metribuzin field accumulation study (§165-2) is reserved pending review of the confined accumulation study.

In addition, the following policy regarding rotational crops should be brought to the registrant's attention:

- a. If residues are expected in rotational crops planted one year or more after application of metribuzin, then a rotational crop tolerance should be requested.
- b. Also, the registrant may apply for a rotational crop tolerance at any interval that results in residues and request a waiver from the field rotational crop study.

8. BACKGROUND:

A. Introduction:

The Registration Standard for Metribuzin was published in June 1985. Data were found to be lacking to determine the time intervals at which rotated crops planted in treated areas would be free of pesticide residues. A review of 103 rotational crop studies (E. Regelman, 11/5/85) concluded that all were invalid and lack soils data.

B. Directions for use:

Metribuzin is a selective, triazine herbicide registered for use on a variety of field crop, vegetable crop, turf (bermuda grass), and a terrestrial non-crop (including railroad rights-of-way) sites. Of the

total amount of metribuzin applied in the U.S., based on a 1984 estimate, 94% was used on soybeans, with 1.8, 1.5, and 1.2% used on potatoes, wheat, and sugarcane, respectively. Application rates range from 0.13-2.0 lb ai/A on most field and vegetable crops, 2-6 lb ai/A on sugarcane, and 1.0-7.5 lb ai/A on noncrop sites. Metribuzin is only formulated as single active ingredient products. Single active ingredient formulations consist of 50, 70, and 75% WP, and 4 lb/gal FIC. Metribuzin may be applied broadcast or in a band using ground equipment and may also be applied aerially or by sprinkler irrigation systems (potatoes). Metribuzin may be soil incorporated, surface applied, or applied foliarly.

MEMORANDUM

SUBJECT: Request for a Time Extension for Submission
of the Report of a Study Required under
FIFRA 3(C)(2)(b): METRIBUZIN

FROM: John J. Neylan III, Acting Director
Laboratory Data Integrity
Assurance Division (EN-342)

TO: Edwin F. Tinsworth, Acting Director
Registration Division (TS-767C)

Mobay Corporation, the registrant for metribuzin, has requested a time extension for the submission of a study required under the Registration Standard.

The specific reasons for requesting the extension are detailed in the enclosed letter from John S. Thornton.

The study involved and the new date requested is:

Field accumulation on rotational crops
from 2/28/89 to "reserved" pending the Agency's
review of the confined crops study.

RECEIVED
11/8/89

Please inform me by December 28, 1988 of your decision on this request so that I may inform the registrant.

Please provide your decision in the form of a letter to the registrant. The signature line, as previously agreed, should be:

Sincerely yours,

A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

Attachment

cc: Geraldine Werdig (TS-767C)
Roberta Pohl

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

P.O. Box 4913
Hawthorn Road
Kansas City, MO 64120-0013
Cable: Kemagro Kansas City
Telephone: 816/242-2000

Subject: Reregistration of Metribuzin Herbicide Products
Request for Extension of a Data Requirement

September 30, 1988

Gentlemen:

Mobay hereby requests that the Agency extend the timeframe for submitting field accumulation data on rotational crops (EPA Guideline No. 165-2) for the reasons discussed below. The registration standard guidance document for metribuzin requires submission of a field accumulation study on rotational crops within 50 months of issuance. We propose that the field study with metribuzin should not be required until the Agency has completed review of the confined accumulation study (Mobay Report No. 98324) submitted on September 30, 1988 to Mr. Robert J. Taylor, Product Manager (25).

1. The requirement for confined accumulation data on rotational crops (EPA Guideline No. 165-1, page 69 of Table A in the metribuzin registration standard guidance document) is referenced to Footnote 15A (page 70) which reads "Conditional on results from confined study." (Please see enclosed copy of pages 69 and 70 of the guidance document). We assume that Footnote 15A is intended to apply to the requirement for field accumulation data on rotational crops (EPA Guideline No. 165-2, page 69 of Table A), but the Agency needs to clarify this point. Obviously, it is illogical to make the requirement for a confined accumulation study "conditional on results from confined study." Further on this point, we would add the observation that 40 CFR Part 158 states "Field accumulation study is required if significant residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study" (emphasis added).

2. Given that the requirement for a field rotational crop study is conditional on results of the confined accumulation study, the metribuzin registration standard guidance document should not have specified a 50 month timeframe for submission of the field study. Instead, this data requirement should have been listed in Table A as "reserved" pending the Agency's review and evaluation of the confined accumulation study with metribuzin. Any action other than this is inconsistent with the Agency's policies and Part 158 regulations covering data requirements for registration of pesticide products.

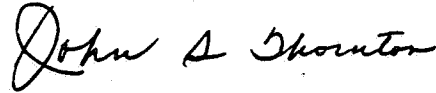
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10/5/88

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Because of the importance of this request for an extension of the timeframe for submitting the field accumulation study we also ask that the Agency review this matter as soon as possible and advise Mobay of its decision.

Yours very truly,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION



John S. Thornton, Manager
Registrations
Research and Development

Enclosure:

Pages 69 and 70 of Metribuzin Registration Standard Guidance Document.

cc: Mr. Robert J. Taylor
Product Manager (25)

TABLE A
GENERIC DATA REQUIREMENTS FOR METRIBUZIN

Data Requirements	Composition ^{1/}	Use ^{2/} Pattern	Does EPA Have Data To Satisfy This Require- ment? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframes For Data Submission ^{3/}
<u>§158.130 Environmental Fate - Continued</u>					
<u>DISSIPATION STUDIES-FIELD:</u>					
164-1 - Soil	TEP	A, B	No		Yes ^{3A/} 27 Months
164-2 - Aquatic (Sediment)	TEP		No		No ^{11/}
164-3 - Forestry	TEP		No		No ^{12/}
164-4 - Combination and Tank Mixes			No		No ^{13/}
164-5 - Soil, Long-term	TEP	A	No		No ^{14/}
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes ^{15A/} 39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Yes ^{15/} 50 Months
165-3 - Irrigated Crops	TEP		No		No ^{16/}
165-4 - In Fish	TGAI or PAIRA	A, B	No		Yes 12 Months
165-5 - In Aquatic Nontarget Organisms	TEP		No		No ^{17/}

MONITORING STUDIES:

Ground water Monitoring
Studies

69^{NO}

Yes^{18/}

- 1/ Composition: TGA1 = Technical grade of the active ingredient; PAIFA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.
- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-food; C = Aquatic, Food Crop; D = Aquatic, Non-food; E = Greenhouse, Food Crop; F = Greenhouse, Non-food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
 - ° 9 Month Due Date 1s March 31, 1986
 - ° 12 Month Due Date 1s June 30, 1986
 - ° 27 Month Due Date 1s September 30, 1987
 - ° 39 Month Due Date 1s September 30, 1988
 - ° 50 Month Due Date 1s February 28, 1989
- 3A/ Data in response to the Data Call-In for groundwater including hydrolysis, photodegradation in water and on soil, aerobic and anaerobic soil metabolism, mobility, and field dissipation have been received and screened. Any valid studies which meet guidelines will reduce the data gaps.
- 4/ This study will be acceptable if additional data are provided on the factors affecting the incident sunlight as well as its intensity and duration.
- 5/ This compound does not require data on photodegradation in air.
- 6/ Data are not required because metribuzin has no forestry, or aquatic use.
- 7/ Data are not required because metribuzin has no aquatic use.
- 8/ Additional data are needed on the leaching or adsorption/desorption of the soil degradation products of metribuzin.
- 9/ The compound does not require volatility (lab) data.
- 10/ The compound does not require volatility (field) data.
- 11/ Data are not required because metribuzin has no aquatic uses.
- 12/ Data are not required because metribuzin has no forestry uses.
- 13/ Data requirements for combination products and tank mixes are not addressed in this Standard.
- 14/ Data are not required since results of the valid terrestrial field dissipation data indicated that greater than 50% of the residues dissipate prior to recommended subsequent application.
- 15/ For crops rotated on treated areas, any one of the following would apply:
 - a. A tolerance must be obtained for the rotated crop.
 - b. The product label must include a restriction against the rotation of crops used for feed or food which are not registered for use with metribuzin.
 - c. Data must be provided to determine time intervals at which rotated crops planted in treated areas will be free of pesticide residues.
- 15A/ Conditional on results from confined studies.
- 16/ No data are required because metribuzin does not have an aquatic food crop or aquatic noncrop use is not used in and around holding ponds used for irrigation purposes, and has no use involving effluents or discharges to water used for crop irrigation.
- 17/ No data are required because metribuzin has no forestry aquatic noncrop, or aquatic impact use.
- 18/ Ground water monitoring studies will be required. Notification of types of studies required and sites to be tested (Agency is in process of determining types of studies and test sites), by means of an amendment to the standard 3 months of issuance of the standard. A time limit for submission of data will be set at that time.